CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-517/S-031

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW | **1. ORGANIZATION** DAIDP (HFD-520) | **2. NDA NUMBER** 50-517

3. NAME & ADDRESS OF APPLICANT
Merck Sharp & Dohme Research Lab.
Sumneytown Pike
West Point. PA 19486

4. AF NUMBER
-

5. SUPPLEMENT(s) NUMBER(s) DATE(s)
SLR-031, 11/8/91

6. NAME OF DRUG
Mefoxin

7. NONPROPRIETARY NAME
Cefoxitin Sodium

8. SUPPLEMENT(s) PROVIDES FOR:
S-031 provides for labeling revision

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES

10. PHARMACOLOGICAL CATEGORY
Antibiotic

11. HOW DISPENSED
XXX
Rx OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Solution, sterile

14. POTENCY(ies)
1g/10ml

15. CHEMICAL NAME AND STRUCTURE

m.w. 449.43
CAS Registry No. - -

16. RECORDS AND REPORTS

	CURRENT		REVIEWED	
	Yes	No	Yes	No

17. COMMENTS

This drug is the subject of a compendial monograph, USP XXII, pg. 253. This is a CHANGE BEING EFFECTED SUPPLEMENT.

The powder filling was carried out under nitrogen purging in the submission dated 9/12/78

[redacted]

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 50-517/S-31
HFD-520 HFD-520/Debellas
HFD-520/Osterberg HFD-520/Leissa
HFD-520/Tso HFD-520/WHDeCamp:R/D initiale/S/ 12/31/92
HFD-520/Sheldon

19. NAME	**REVIEWER SIGNATURE**	**DATE COMPLETED**
S. C. Tso, Ph.D.	/S/	Sept. 29,1992 /S/ 12/31/92

32. **Labeling**

APPROVABLE.

The package insert has been revised as follow:

* Update the American Hospital Formulatory Service Category to the current category in the A.H.F.S. Drug Information '90.
  Proposed label is A.H.F.S. Category 8:12:07, 7057129.
* Add " to the description of the product to comply with the general Notices and Requirements of Statement I of USP XXII.
* Under COMPATIBILITY AND STABILITY, there are three minor editorial revisions, and revision footnote regarding VIAFLEX to reflect the corporate identification changes of Baxter Healthcare Corporation.
* Under HOW SUPPLIED section:
  1.
* 2. Add "infusion bottles" to National Stock Number description for product Nos. 3368 and 3369.
  3. Add National Stock Numbers for product Nos. 3348 and 3349.

This drug product was approved in Oct. 18, 1978 as sterile cefoxitin sodium which confirms to the standards prescribed by the proposed 21 CFR 442.14a and 442.214 for potency, sterility, nonpyrogenicity, safety, moisture content, pH, identity, and crystallinity. Commitment was made then by the Firm in a telephone conversation on 9/1/78 with Dr. James King that " "; and this commitment was reviewed by Dr. James R. King as acceptable for approval. Also noted in the submission dated 9/12/78, under sterile packaging of sodium cefoxitin operation manual, the powder filling was carried out under nitrogen purging.

APPEARS THIS WAY
ON ORIGINAL